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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,869	05/14/2001	Howard Federoff	176/60088 (6-11406-600)	9948

7590 05/29/2003

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EXAMINER

CROUCH, DEBORAH

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 05/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,869

Applicant(s)

FEDEROFF, HOWARD

Examiner

Deborah Crouch, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 67-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 67-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Applicant's arguments filed April 8, 2003 in paper no. 6 have been fully considered but they are not persuasive. The amendment has been entered.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 67-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,252,130 B1.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because present claims 67-76 are generic to all that is recited in claims 1-18 of U.S. Patent No. 6,252,130 B1. That is claims 1-18 of '130 fall entirely within the scope of present claims 67-76 or, in other words, claims 67-76 are anticipated by claims 1-18 of '130. The present claims are generic to those of '130 because the present claims to methods involving mammals

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encompass the claims in '130 to methods involving nonhuman mammals and nonhuman mammal products. "Mammal" is a genus to the species "nonhuman mammal."

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 67-76 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of activating a gene to be expressed in a recombinatorial substrate and methods of activating a recombinatorial substrate comprising providing a transgenic mouse carrying a DNA molecule comprising a recombinatorial substrate, does not reasonably provide enablement for methods of activating a gene to be expressed in a recombinatorial substrate and methods of activating a recombinatorial substrate comprising providing a transgenic mammal carrying a DNA molecule comprising a recombinatorial substrate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to methods of activating a gene to be expressed in a recombinatorial substrate and methods of activating a recombinatorial substrate comprising providing a transgenic mammal carrying a DNA molecule comprising a recombinatorial substrate.

Applicant argues that transgenic mammals can be produced by transfection of embryonic stem cells instead of pronuclear injection. Applicant supplies references Lamb et al, Kong et al, and Wheeler et al. Applicant argues that transfection of embryonic stem cells is disclosed in the specification. Applicant argues that Lamb, Kong and Wheeler each discuss the limitations of pronuclear injection in that targeting of the transgene is not possible.

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Applicant argues that Wheeler notes that embryonic stem cells are known for a variety of species including human. Applicant argues that using such cells together with the constructs and techniques of the present application would enable one of ordinary skill in the art to make and use the claimed invention. These arguments are not persuasive.

Enablement has to be established at the time of filing, which for the present application is November 13, 1995. The art supplied by applicant and the art supplied herewith clearly indicate that ES cells were not available at the time of filing for use in making the claimed transgenic mammals. With regard to Wheeler's specific disclosure of pig ES cells, it should be recognized that the putative pig ES cells gave rise to chimera but there is no disclosure that the chimera gave rise to a pig of the ES cell phenotype (pages 1351-1352). Further, Wheeler states, in reference to ES cells recently isolated and the production of swine and cattle chimera, "validation of totipotency of these embryo-derived ES cell lines awaits conformation (page 1351, parag. 1, last sentence). Thus, the totipotency of these cells was not known at the time of the Wheeler publication in 2001, six years after applicant's earliest priority date. This totipotency is critical to the implementation of the claimed invention, and the evidence provided by Wheeler indicates that the critical ES cells were not known six years post-priority, much less at the time of priority. Additional art references indicate that at the time of filing, only mouse ES cells were regarded by the art to be totipotent, that is only mouse ES cells were known to contribute to the germ line. Moreadith states that in 1997, that several putative ES cells lines had been isolated from hamster, pig, sheep, cattle, rabbit, rat, mink, monkey and humans, but Moreadith also states that the technology in 1997 was limited to mice (page 214, col. 1, parag. 3, lines 5-12). Prella states in 1999, that many embryo-derived cell lines resemble morphologically mouse ES cells, and have the ability to differentiate in vitro, but there is no evidence of live born, fertile germ line chimeras in mammalian species other than mouse (page 222, col. 2,

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parag. 1, lines 10-16). Gardner states in 1997 that attempts had been made to produce ES cells from pre-implantation embryos in many mammals, that cells resembling mouse ES cells morphologically, in marker expression, growth characteristics and differentiation in vitro and in vivo have been obtained, but the question left unanswered is if these cells can contribute to gamete formation, the key attribute of ES cells (page 235, col. 1, parag. 2, col. 2, lines 3). Also, Gardner summarizes non-mouse ES cells in Table 1, and indicates that there is no evidence of germ line colonization in rat, rabbit, hamster, mink, rhesus monkey, pig, cow or sheep (Table 1, page 236). None of applicant's supplied references support the enablement of non-mouse stem cells as useful for producing the claimed invention.

The claims are free of the prior art. At the time of filing, the prior art did not teach or suggested methods of methods of activating a gene to be expressed in a recombinatorial substrate and methods of activating a recombinatorial substrate comprising providing a transgenic human carrying a DNA molecule comprising a recombinatorial substrate.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no

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event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 703-308-1126. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

dc
May 22, 2003



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